

REMARKS

Applicant respectfully requests reconsideration. Claims 19-37 were previously pending in this application. By this amendment, Applicant is canceling claims 19-37 without prejudice or disclaimer and solely in the interest of advancing prosecution. Applicant reserves the right to pursue the cancelled subject matter in one or more continuation or divisional applications. New claims 38-43 have been added. Support for the new claims is found in the original claims and the specification as filed. For example, support for claims 38-41 is found at least at page 5, lines 7-13; page 15, lines 8-22; original claim 1; and SEQ ID NO: 46 of the sequence listing; and support for claims 42 and 43 can be found at least at page 6, lines 13-29 and in original claims 12 and 17. As a result, claims 38-43 are pending for examination with claim 38 being an independent claim. No new matter has been added.

Foreign Priority

The Examiner acknowledged Applicant's request for priority to China Patent Application No. 02136766.3, filed September 2, 2002. Applicant has accordingly amended the specification herein to reflect this priority claim.

Restriction Requirement

The Examiner acknowledges election of Group I (Claims 19-29, and 36) with further election of the species SEQ ID NO: 46. By this amendment, Applicant has cancelled claims 19-29, and 36, and presents new claims 38-43, which read on the claims of Group I and the elected species, SEQ ID NO: 46. Again, Applicant reserves the right to pursue the cancelled subject matter in one or more continuation or divisional applications.

Claim Objections

The Examiner has objected to claim 20, indicating that the peptides should be identified by an appropriate sequence identifier. By this amendment, Claim 20 is now cancelled. Applicant present new claims 38-43 that recite an amino acid sequence as set forth in SEQ ID

NO: 46. In this regard, Applicant believes that the objection is now moot. Accordingly, withdrawal of the objection is respectfully requested.

Rejections under 35 U.S.C. §112

The Examiner rejected claim(s) 19-29 and 36 under 35 U.S.C. §112, first paragraph, because, according to the Examiner, the specification, while being enabling for methods and compositions of SEQ ID NO: 46 (a synthetic antimicrobial peptide) to treat an infectious disease induced by bacteria, fungi, and/or viruses, does not reasonably provide enablement for functional analogs, fragments or derivatives of SEQ ID NO: 46 that have antimicrobial activity and can treat an infectious disease induced by bacteria, fungi, and/or viruses. Applicant respectfully traverses.

Without conceding and solely in the interest of expediting prosecution, Applicant has cancelled claims 19-29 and 36 without prejudice or disclaimer and presents new claims 38-43. Applicant asserts that the specification is enabling for the pending claims including the full genus of the claimed antimicrobial peptides.

At the time the application was filed, the state of the art was such that peptide production methods were well known and certain peptides were known to be effective at killing microorganisms. The instant invention is based, in part, on the discovery of a series of new peptides with desirable antimicrobial properties. Thus, the nature of the invention relates to antimicrobial peptides comprising defined amino acid sequences (Claims 38-41) as well as methods for the production (Claim 42) and use (Claim 43) of those peptides. The breadth of the claims embraces a genus of antimicrobial peptides that comprise a sequence as set forth in SEQ ID NO: 46, which has an invariable portion of 11 amino acids (11-mer) bound to a variable portion of 12 amino acids (12-mer), the amino acid residues of which may vary according to a set of prescribed rules. Those skilled in the art, guided by the instant specification, could readily produce and use the full scope of the claimed antimicrobial peptides using techniques that were routine in the art. In addition, the specification as filed provides sufficient guidance on how to make the claimed peptides by disclosing exemplary peptide production methods, including solid-phase polypeptide synthesis and recombinant DNA technology (*See, e.g.*, specification at page 6, lines 13-16). The skilled artisan could readily produce and identify members of the claimed

genus with the requisite antimicrobial activity using no more than routine experimentation. In this regard, the specification provides a series of working examples, in which exemplary members of the claimed genus are synthesized and shown to inhibit growth of various microbial organisms both *in vitro* (See, e.g., specification at page 13-16, Examples 4-5) and *in vivo* (See, e.g., specification at page 17, Example 8). Two of the exemplary peptides have substantially different variable regions (GK-1 and GK-2) and a third represents a cyclization derivative (GK-20). Thus, the exemplary antimicrobial peptides reveal predictable results among divergent members of the claimed genus. In view of at least the foregoing, Applicant asserts that the specification is enabling for new claims 38-43. Accordingly, withdrawal of the rejection is respectfully requested.

Written Description

Claims 19-29, and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

While Applicant respectfully traverses the rejection, claims 19-29, and 36 are hereby cancelled without prejudice or disclaimer. As noted above, Applicant presents new claims 38-43 that recite a synthetic antimicrobial peptide comprising an amino acid sequence as set forth in SEQ ID NO:46. Applicant asserts that the specification provides adequate written description support for the pending claims including the full genus of antimicrobial peptides.

"The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus." (Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement, Federal Register, Vol. 66, No.4, page 1106 3rd column, Friday, January 5, 2001.)

The claims as now pending recite a synthetic antimicrobial peptide comprising an amino acid sequence as set forth in SEQ ID NO:46. Members of this genus are identifiable, in part, by a characteristic 11-mer portion having the sequence: Lys Trp Lys Leu Phe Lys Lys Ile Gly Ile

Gly. Members of the genus are further identifiable by a characteristic 12-mer variable portion, which is bound to the C-terminal glycine of the 11-mer portion, and which has a sequence conforming to a prescribed set of rules that are set forth in the sequence listing. In addition, the specification discloses an actual reduction to practice of a representative number of species. For example, the specification discloses the production of GK-1, GK-2 and GK-20, which is a cyclization derivative of GK-1. (*See, e.g.*, specification at page 5, lines 3-13; page 6-7, Example 1; and page 15, Example 5.) The specification further discloses functional characteristics of exemplary members of the claimed genus of antimicrobial peptides. (*See, e.g.*, specification at pages 8-18, Example 2-9). In view of the foregoing, Applicant submits that the written description requirement is satisfied. Accordingly withdrawal of the rejection is respectfully requested.

According to the Examiner, Claims 19-20, and 36 are rejected separately under 112 first paragraph for lack of adequate written description, because the claims refer to a peptide only by function and not in terms of structure. The Examiner stated that, although Applicant had elected SEQ ID NO: 46, the sequence was not recited in base claim 19 and, therefore, the rejection *may* apply. Applicant submits that this rejection is not applicable to the pending claims at least because claim 38, from which all other claims depend, recites a synthetic antimicrobial peptide comprising an amino acid sequence as set forth in SEQ ID NO:46 and, thereby, refers to the antimicrobial peptides by sequence. The claimed peptides all have this structure in common. Accordingly, withdrawal of the rejection is respectfully requested.

Indefiniteness

Claims 19-29, 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. As noted above, claims 19-20, and 36 are hereby cancelled without prejudice or disclaimer. Applicant trusts that in view of new claims 38-43, the rejection is now moot. Accordingly, withdrawal of the rejection is respectfully requested.

Rejections Under 35 U.S.C. §102

The Examiner rejected claims 19-20, 21-25, 29 under 35 U.S.C. §102 as being anticipated by Scott et al. (1999 Infection and Immunity 67(4): 2005-2009; IDS 03.23.06) ('Scott'), and also rejected claims 19-20, 26-28 under 35 U.S.C. 102(e) as being anticipated by Hahm et al. (US6800727) ('Hahm').

While Applicant respectfully traverses both rejections, as noted above, claims 19-29 are hereby cancelled without prejudice or disclaimer. Applicant presents new claims 38-42 that covers synthetic antimicrobial peptides comprising an amino acid sequence as set forth in SEQ ID NO:46 and methods of producing such peptides. Neither Scott nor Hahm disclose a peptide comprising an amino acid sequence as set forth in SEQ ID NO:46. Thus, neither reference anticipates the pending claims. Accordingly, withdrawal of the rejection is respectfully requested.

Rejections Under 35 U.S.C. §103

The Examiner rejected claim 36 under 35 U.S.C. §103(a) as being unpatentable over Scott (cited above). The Examiner asserts that Scott teaches a series of synthetic antimicrobial peptides comprising a core structure of 2 sets of a 4-mer or 3 sets of a 4-mer. According to the Examiner, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the synthetic antimicrobial peptides of Scott to a subject having a bacterial infection, because Scott teaches that synthetic antimicrobial peptides can be used to treat bacteria growth and can be used in combination with antibiotics.

While Applicant respectfully traverses the rejection, as noted above, claim 36 is hereby cancelled without prejudice or disclaimer. Applicant presents new claim 43 that covers a method for treating infectious disease induced by bacteria, fungi, and/or viruses. The method of claim 43 involves administering an effective amount of a synthetic antimicrobial peptide comprising an amino acid sequence as set forth in SEQ ID NO:46. Applicant submits that Scott does not render claim 43 obvious, because the reference at least does not teach or suggest the antimicrobial peptides of the claimed method.

For a prior art reference to render a claim obvious there must at least be "a suggestion of all limitations in a claim". CFMT, Inc. v. Yieldup Intern. Corp., 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing In re Royka, 490 F.2d 981, 985 (CCPA 1974)). Scott does not teach a peptide

comprising an amino acid sequence as set forth in SEQ ID NO:46. Moreover, Scott provides no reason or basis for a skilled artisan to produce an antimicrobial peptide comprising an amino acid sequence as set forth in SEQ ID NO:46. Thus, for at least the foregoing reasons, Scott does not render the method of claim 43 obvious. Accordingly, withdrawal of the rejection is respectfully requested.

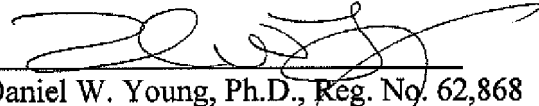
CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. H0757.70000US00.

Respectfully submitted,

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